



Enzo Biochem, Inc.,
527 Madison Avenue
New York, NY 10022
212.583.0100
fax. 212.583.0150

facsimile cover letter

date: July 23, 2003 (4:15 P.M.)
name: Examiner Ardin H. Marschel, Ph.D. (Group Art Unit 1631)
organization: United States Patent and Trademark Office
fax number: 703-746-4991
from: Ronald C. Fedus, Esq.
U.S. Patent Application Serial No. 08/479,995
Pergolizzi et al. (inventors)
Filed: June 7, 1995
re: Our Ref.: Enz-11(C2)(D1)(C2)
number of pages
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IMPORTANT!

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ACCOMPANYING FOUR (4) PAGES TO:**

**EXAMINER ARDIN H. MARSCHEL, Ph.D.,
GROUP ART UNIT 1631.**

THANK YOU.

Dear Dr. Marschel:

This is a follow-up to our interview held on July 1, 2003.

You may recall that you raised some points at the interview in regard to the claim language in Serial No. 08/479,995 when viewed against the other U.S. patents which are the subject of our §607 Request For Interference. After consulting with our interference attorneys, we prepared an informal discussion paper directed to those points. We also reviewed the allowed claims in the '995 application against those other U.S. patents, and we think that the points you raised were the most salient points in that regard.

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Examiner Ardin H. Marsch I, Ph.D. (Group Art Unit 1631)
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Finally, as referenced in the accompanying document, we are filing today a Third Request For Interference, together with an amendment. The Third Request includes only minor changes to the previous request and the Amendment only adds two claims that are nearly identical to claims that were added on March 28, 2003.

Please do not hesitate to contact us if you have any questions or comments, or if further information is required.

Cordially,



Ronald C. Fedus
Registration No. 32,567
Attorney for Applicants

Accompanying enclosure (4 pages)

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**PERGOLIZZI ET AL., U.S. PATENT APPL. SERIAL NO. 08/479,995
(FILED JUNE 7, 1995)**

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Points Raised at the July 1, 2003 Interview

During the interview held on July 1, 2003, several points were raised about claim terms in the Pergolizzi '995 Application and in the context of the four U.S. patents against which Applicants seek an interference. As understood by Applicants' attorney and their representative, some thoughts on these points are provided below. The information below is not intended to be a formal response or filing to any communication, nor should it be taken as necessarily exhaustive. Rather, it is being provided to help clarify the points raised at the July 1, 2003 interview. Hopefully, it will be of some assistance to the Examiner as this case moves forward.

Point #1

The claims in Chiswell's U.S. Patent No. 4,716,106 ("the Chiswell claims") do not recite non-radioactive labels. Chiswell's claim 1 is identical to Count 1. Are the Pergolizzi claims that are designated as corresponding to Count 1 properly designated under 37 C.F.R. §1.60(n)?

Discussion of Point #1

Yes. The Pergolizzi claims that correspond to Count 1 do not recite non-radioactive labels.

Any confusion may be attributable to the fact that Pergolizzi's claims 538-539 recite non-radioactive labels. These claims are designated as corresponding to Count 3, which is directed to a kit. The kit recited in Count 3 currently does not recite non-radioactive labels. However, Applicants are amending Count 3 to specifically recite non-radioactive labels. Applicants are filing a Third Request for Interference. Count 3 of the Third Request is otherwise the same as Count 3 of the Second Request for Interference that was filed on March 28, 2003. The other counts remain completely the same in the Third Request. (The Third Request includes only minor changes and is mainly being filed for housekeeping reasons.)

There are two key criteria for entering into an interference. The first criterion is that one of the applicant's claims is in condition for allowance. The second criterion is that this claim is directed to the same invention as, or an obvious variation of, the invention defined by one or more claims of the patent, and *vice versa*. The first criterion is satisfied because the Examiner has already advised that the claims designated as corresponding to Count 1 are in condition for allowance, insofar as they all depend on claims previously indicated to be allowable. The second criterion is satisfied because both sets of claims -- Pergolizzi's and

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Chiswell's -- recite the method without reference to a non-radioactive label and are otherwise directed to the same invention or an obvious variant thereof.

Point #2

Unlike the corresponding patent claims and proposed counts, the Pergolizzi method claims explicitly recite that the signaling entities are substantially incapable of binding or hybridizing to the target analyte. Are these Pergolizzi method claims -- and their explicit recitation that the signaling entities are substantially incapable of binding or hybridizing to the target analyte -- directed to the same patentable invention as the patent claims and the proposed counts which do not explicitly recite this aspect of the invention?

Discussion of Point #2

That the signaling entities are substantially incapable of binding or hybridizing to the target is implicit or inherent in the patent claims and proposed counts. If the signaling entities were substantially capable of binding or hybridizing to the target, they would defeat one of the main purposes of the common invention -- universality conferred by a generic binding site for generic signaling entities.¹

For example, Count 2, Count 3 and the claims in the Schneider patents (US 4,882,269 and US 5,424,188) recite that the bridge ("primary probe") binds to the signaling entities ("secondary probes") via the bridge's "polymeric tail," which is "incapable of binding to the target." Since the polymeric tail is complementary to the secondary probes, and since the polymeric tail cannot bind to the target, then it stands to reason that the secondary probes cannot substantially bind to the target.²

Similarly, Count 1 and the Chiswell claims recite that the signaling entity ("labelled polynucleotide secondary probe") has a complex sequence and that the bridge ("primary probe") has two sections: one section that is complementary to the target and one section that is complementary to the complex sequence of the signaling entity. These definitions are largely inconsistent with the possibility of the signaling entity of Count 1 or of the Chiswell claims being capable of binding to the target.

¹ See, e.g., Chiswell patent, col. 2, lines 1-10; Schneider '269 patent, col. 2, lines 23-31 and 47-49, col. 7, lines 18-22; Schneider '188 patent, col. 2, lines 27-35 and 51-53, col. 7, lines 23-27; Urdea patent, col. 2, lines 6-13, col. 14, lines 39-41.

² The signaling entities could bind to the target if the target were identical or highly homologous to the polymeric tail. But this would be anathema to the common invention.

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Count 4 and the claims of Urdea's US 5,124,246 also inherently include this feature. Urdea's claims recite that the first part of the bridge ("multimer") is actually hybridized to the target and that the signaling entities ("labeled oligonucleotides") are actually hybridized to the second part of the bridge ("second oligonucleotide units"). This is inconsistent with the possibility of the signaling entities binding to the target.

As was the case with Point #1, the two criteria for interference are met with respect to the subject matter of Point #2, namely, allowable subject matter and inventions that are not separately patentable in view of each other.

Point #3

Pergolizzi's method claims 532-537 and 540-541 refer to providing a composition comprising the bridge and the signaling entity, and then "forming a complex" comprising the composition and the target. Are the relevant patent claims, which do not recite a "complex," directed to the same patentable invention as the above-cited Pergolizzi method claims?

Discussion of Point #3

Despite not reciting "complex" (as a noun), the relevant patent claims explicitly recite or implicitly include formation of such complexes. Formation of such complexes is the whole point of the common invention.

For example, claim 1 of Chiswell's '106 Patent (Count 1) recites (b)(i) contacting the target with the bridge under hybridization conditions, and (b)(ii) hybridizing the signaling entity to the bridge before, during or after step (b)(i).

Similarly, claim 1 of Schneider's '269 Patent (Count 2) recites (a) contacting the target under hybridization conditions with the bridge and the signaling entity, and (b) detecting the signal generated by the "reaction product" formed in step (a) in which both the target and the signaling entity are bound to the bridge.

Likewise, claim 1 of Urdea's U.S. Patent No. 5,124,246 (Count 4) recites (II) that the bridge is hybridized to the target, and (IV) the signaling entity is hybridized to the bridge.

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Once again, Applicants have established the existence of the two necessary criteria for declaration of an interference, namely, allowable claims and overlapping subject matter.

Point #4:

Are the "labels" and "signal generating components" as used in the patents and the application equivalent to each other?

Discussion of Point #4:

Yes, these terms are equivalent in all of the patents and the application. Specific labels and signal generating components are not the heart of the common invention. On the contrary, the heart of the common invention is the very ability to use generic signaling entities. Accordingly, the disclosure of labels and signal generating components is fairly conventional in the patents and the application.³

Again, therefore, the two criteria for interference are satisfied.

* * * * *

³ See, e.g., Chiswell, col. 1 and 3; Urdea, col. 1, 16-18, 27-28 and 38-39; Schneider '188, col. 2, 4, 10, 13-15, 18-22, and Fig. 5 and 6; Schneider '269, col. 2, 4, 10, 13-15, 18-22, and Fig. 5 and 6; Pergolizzi Application, pp. 1-6, 17-22 and 34-57.

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